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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/805,913

03/22/2004

Ashley J. Birkett

91645

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24628 7590 10/30/2007

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EXAMINER

PENG, BO

ART UNIT

PAPER NUMBER

1648

MAIL DATE

DELIVERY MODE

10/30/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/805,913

Applicant(s)

BIRKETT, ASHLEY J.

Examiner

Bo Peng

Art Unit

1648

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 August 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 101-109 and 116-118 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 101-109 and 116-118 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>8/21/07</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. This Office Action is in response to the amendment filed August 21, 2007. Claims 116, 117 and 118 are amended. Claims 101-109 and 116-118 are pending, and are under consideration in this Office action.

Claim Rejections - 35 USC § 112, first paragraph

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. The rejection of Claims 101-109 and 116-118 under 35 U.S.C. 112, first paragraph, for introduction of new matter, is **withdrawn** in view of the deletion of the new matter.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. The rejection of Claims 101-109 and 116-118 under 35 U.S.C. 103(a), as being unpatentable over Pumpens et al. (1995) in view of Zlotnick et al (1997), is **maintained**.

6. Applicant argues again that Ulrich, as ordinary skill in the art, who stated that the

Art Unit: 1648

stability problem of HBc was not solved, did not suggest that the desired stability could be achieved by combining teachings of both Pumpens and Zlotnick, but rather maintained that the problem still had to be solved.

7. The response to this argument was set forth in the previous Office action (See Para 15).

8. Applicant further argues that Zlotnick's Cp*150, which is an HBc Δ containing a cystine at its C-termini, is not stable.

9. In response to Applicant's argument, all structure limitations of the instant claims contain such structural features taught or suggested by Pumpens and Zlotnick. Applicant has not explicitly pointed out what are the specific structural features of the alleged HBc chimera that are different from those of the prior art, which contribute alleged enhanced stability of the claimed HBc chimera.

10. It is noted that Applicant has amended Claims 1, 18, 42, 51 and 63 as recited: "wherein said particle stability is assayed as a measurement of the percentage of full length chimera molecules determined by Coomassie Blue stain of reducing buffer 15%SDS-PAGE results obtained after dilution of purified particles to a concentration of 1 mg/mL in aqueous 50 mM NAP04, pH 6.8, with sodium azide added to a final concentration of 0.02% and incubation at 37° C for about 14 days."

11. However, the amendment does not constitute a structural or functional limitation to the alleged HBc chimera because the amendment is directed to a method of measuring an HBc particle, which does not change the structural or functional characteristics of the alleged chimera HBc. Thus, the rejection is maintained.

Art Unit: 1648

Remarks

12. No claim is allowed. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bo Peng, Ph.D. whose telephone number is 571-272-5542. The examiner can normally be reached on M-F, 9-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell, Ph. D. can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

BP
Bo Peng, Ph.D.
October 29, 2007

/Bruce Campell/
Bruce Campell
Supervisory Patent Examiner
Art Unit 1648